

REMARKS

Claims 18, 19, 23, 26, 27, 30, 55 are currently amended. Claims 1-17, 29, 32-51 and 54 are hereby cancelled. Claims 20-22, 24, 25, 28, 31, 52 and 53 remain unchanged.

Claim rejection under 35 USC 112.

The Examiner has rejected claim 26 for the use of the word “auxiliary ” to qualify a radiopaque marker. In amended claim 26, the phrase “auxiliary radiopaque marker” has been replaced by “a dilator/sheath radiopaque marking“ which the Applicant submits is supported by the specification. For example, paragraph 53 of the specification mentions that the dilator and the sheath may have a radiopaque marking. In view of the above, the Applicant respectfully requests that this rejection of claims 26 be withdrawn.

Claim rejection under 35 USC 102

The Examiner has rejected claims 18-21, 24-25, 27-30 and 52-55 as being anticipated by US Patent 6,032,674 (hereinafter Eggers). In addition, the Examiner has rejected claims 22-23, 26 and 30 as being obvious in view of the combination of Eggers and of US Patent 6, 650, 923 (hereinafter Lesh).

Amended claim 18 includes the following limitation:

- creating said channel through said cardiac septal material by delivering said radio-frequency electrical current from said active electrode to said grounding pad, said radio-frequency electrical current being delivered through said cardiac septal material.

Eggers discloses a device and a method for creating channels through the myocardium, the muscular layer making up the outer peripheral wall of the heart, using radio-frequency electrical current. Eggers emphasizes throughout the disclosure the criticality of limiting the propagation of the current in surrounding tissue, for example by providing means for limiting the current provided by the electrode (for example Col. 10, lines 37-51, Col 11, lines 11-31, among others). Limiting the propagation of current when creating channels in the myocardium, as performed in Eggers, is required to limit the extent of unwanted tissue damage. It is respectfully submitted that the claimed invention is both new and non-obvious in view of Eggers since it provides a new and unexpected result.

Contrarily to the method disclosed in Eggers which is clearly destined to be used for creating channels in the myocardium, the claimed invention is intended to be used in the septal wall separating the right portion of the heart from the left portion of the heart. In addition, Eggers only describes devices and methods wherein an electrical current is circulated between electrodes located in proximity to the material through which the channel is created (see Figures). Eggers never

mentions that the electrical current may be delivered from an active electrode to a grounding pad while passing through cardiac septal material.

This is in complete opposition with the claimed invention, as the use of a grounding pad necessarily requires that the electrical current propagates away from the active electrode and into the body. The Applicant has found the surprising result that delivering radio-frequency electrical current into cardiac septal material from an active electrode to a grounding pad does not cause major unwanted side effects. It is believed that this is caused mainly by the specific anatomy of the septum.

Indeed, the septum of the heart is typically thinner than the myocardium. Also, blood, which typically has a lower impedance than tissue, is present on both sides of the septum. Therefore, when the electrical current is injected into the septum, it does not spread over a large distance before coming into a contact with blood. Because of its low impedance, blood creates a preferential conduction path at the surface of the septum and most of the current at the surface is therefore conducted away from the septum and into the blood. When entering the blood, the electrical current is spread over a relatively large volume before coming into contact with other tissue.

When the current contacts other tissue, such as for example the myocardium, its density has been reduced so as to present only minimal risks of unwanted side

effects. The blood itself has a relatively small impedance and would require a very large current intensity to be heated at a damaging temperature since ohmic power delivery increases with impedance at fixed current. Such current intensities are relatively easy to avoid by controlling the intensity of the current delivered by the active electrode so that the blood does not coagulate away from the septum.

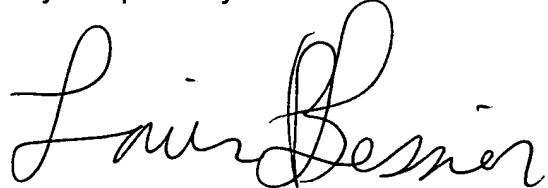
In view of the above, the Applicant respectfully submits that the claimed invention is patentably distinct and innovative in view of Eggers as it is in direct contrast to the invention disclosed in Eggers. In fact, Eggers teaches directly away from the claimed invention.

Regarding Lesh, this document nowhere mentions that an electrical current may be used to create a channel through the septum. To the contrary, Lesh discloses the use of a needle to pierce a hole through a septum. The use of an energy delivery device, for example a device delivering radio-frequency electrical current, to create a channel in a tissue has many advantages over the use of a needle to pierce through the tissue. For example, and non-limitingly, the use such devices reduces the risks of injury to the myocardium that may occur when a needle is pushed with too much force through the septum and continues its advance up to the myocardium after piercing the septum.

Claims 19-28, 30, 31, 52, 53 and 55 all depend directly or indirectly from claim 18 and as such include all the limitations of this base claim. Accordingly, the Applicant respectfully submits that claims distinguish over the art cited by the Examiner for the same reasons as those expressed hereinabove with respect to claim 18. Furthermore, claims 29 and 54 have been cancelled

It is respectfully submitted that when the rejection of the claims is reviewed in light of Applicant's arguments, the invention without a doubt should be considered patentably distinguished over the currently applied references. It is now believed the above application is in order for Allowance and such action would be appreciated.

Very Respectfully submitted,

A handwritten signature in black ink, appearing to read "Louis Tessier".

Louis Tessier; Reg : 45,289

Agent for the Applicant